

### **REMARKS**

This responds to the Office Action mailed on February 25, 2009.

Claims 1 and 11 are amended. Claims 1, 3-6, 8-11, 13-16, and 18-35 are now pending in this application.

Of these pending claims, claims 21-35 are withdrawn as being drawn to a non-elected invention.

#### **Withdrawn Claims 21-35**

In an amended dated April 23, 2009, Applicant added claims 21-35. Claims 21-35 were copied from claims 1-15 of U.S. Application Publication No. 2008/0097540 A1 to Bolea et al., which published on April 24, 2008, based on U.S. Application No. 11/956,685.

On July 20, 2009, Examiner Flory and Applicant's representative, Marvin Beekman, discussed claims 21-35. Examiner Flory indicated that claims 21-35 are independent or distinct from the original claims. As Applicant received an action on the merits for the originally presented claims, claims 1, 3-6, 8-11, 13-16, and 18-20 have been constructively elected by original presentation. Thus, Applicant respectfully withdraws claims 21-35, and reserves the right to pursue these claims in a divisional application.

#### **§ 103 Rejection of the Claims**

Claims 1, 4-6, 8, 11, 14-16 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill et al. (U.S. Patent No. 5,718,208 hereinafter "Hill '208"), or alternatively in view of Gross et al. Claims 1, 3-6, 8-11, 13-16 and 18-20 were rejected under 35 U.S.C. § 103(a) as being obvious over Adams et al. (U.S. Publication 2003/0229380, hereinafter "Adams '380") in view of Gross et al. (U.S. Publication 2003/0045909, hereinafter "Gross 909"). Claims 3, 9, 10, 13, 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill '208. The rejections are traversed and reconsideration is respectfully requested.

Applicant generally reiterates the points made in response to previous office actions with respect to the teachings of the cited references. The responses to Applicant's arguments contained in the present office action are addressed below.

Independent claims 1 and 11 recite a device and method, respectively, that relate to the delivery of multi-site ventricular pacing therapy in conjunction with parasympathetic stimulation for the purpose of reducing ventricular wall stress in order to prevent or reverse undesirable cardiac remodeling. Applicant has previously argued that, although there are some discussions relating to cardiac pacing in the cited references, all of the cited references teach delivering parasympathetic stimulation for the express purpose of decreasing heart rate. Applicant can find no teaching or suggestion in the cited references, however, for delivering the parasympathetic stimulation at the same time that ventricular paces are being delivered in order to prevent the heart rate from decreasing. That, of course, would be expected if the primary reason for delivering the parasympathetic stimulation is to decrease the heart rate. The present office action states that:

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies, i.e., that parasympathetic stimulation would be delivered at the same time that ventricular paces are being delivered, are not and cannot be recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This limitation was discussed previously and removed because it was found that there is no support in the disclosure of the instant application for simultaneous delivery. The claim language simply recites "ventricular pacing therapy in conjunction with parasympathetic stimulation," wherein "in conjunction with" does not require or even imply simultaneous delivery.

Claims 1 and 11 recite that the ventricular pacing therapy is delivered "in conjunction with" the parasympathetic stimulation and further recite that the ventricular pacing is delivered in accordance with a demand pacing mode that prevents the heart rate from being slowed by the parasympathetic stimulation. These limitations are clearly supported by the specification where it is discussed that counteracting of undesirable slowing of the heart rate due to parasympathetic stimulation can be accomplished by several means, including delivering pacing therapy in a demand mode that enforces a minimum heart rate. The limitations can only be understood to mean that the parasympathetic stimulation is delivered simultaneously with the ventricular pacing since that is the only way such pacing can prevent the slowing of the heart rate by the parasympathetic stimulation. By "simultaneously with," Applicant does not mean that each of

the pacing pulses must necessarily coincide with parasympathetic stimulation pulses. Applicant would agree that such a reading of the limitations is not supported by the specification. Rather, the limitations should be understood to mean only that ventricular pacing therapy is delivered while the parasympathetic stimulation is being delivered so that the undesired slowing of the heart rate can be counteracted. It was to make this point clear that the phrase “simultaneously with” was replaced in the claims with “in conjunction with.”

Applicant notes that, as pointed out in the office action, paragraph 193 of the Gross reference discusses the use of a pacemaker as part of a control loop to increase the heart rate when it is for any reason too low. Such increase of the heart rate via pacing, however, does not mean that vagal stimulation is not allowed to decrease the heart rate since that is the purpose of the vagal stimulation discussed in the reference. Claims 1 and 11 have been amended herein in an effort to further clarify this point by explicitly stating that the ventricular pacing is delivered in a manner that counteracts slowing of the heart rate by the parasympathetic stimulation so that no slowing of the heart rate occurs.

With regard to the alleged disclosure by the cited references of multi-site ventricular pacing or to such pacing being well-known in the field, it is Applicant’s position that the prior art does not teach or suggest delivering such pacing together with parasympathetic stimulation for the purpose of reducing ventricular wall stress in order to prevent or reverse undesirable ventricular remodeling. That is, the individual stress reducing effects of pacing therapy and parasympathetic stimulation are augmented by delivering both therapies together. Claims 1 and 11 have been amended herein to make this explicit by reciting that the multi-site ventricular pacing therapy is delivered with a pacing pulse output sequence that pre-excites at least one myocardial region relative to other regions for reducing ventricular wall stress.

In rejecting claims 1 and 11, the present office action also alleges the disclosure by the cited references of controlling the delivery of parasympathetic stimulation as a function of sensed parameters such as cardiac output and exertion level. Such disclosures in the cited references, however, all relate to controlling the delivery of parasympathetic stimulation that is allowed to decrease the heart rate. Applicant finds no teaching or suggestion in the cited references for controlling the delivery of parasympathetic stimulation as a function of cardiac

output and exertion level where the parasympathetic stimulation is delivered in conjunction with pacing therapy so that no slowing of the heart rate occurs.

For the reasons given above, Applicant believes that claims 1 and 11, as amended herein, are not rendered obvious by any combination of the cited references. Applicant can find no combination of elements found in the prior art of record that would result in the device and method as recited by claims 1 and 11. Applicant further believes that the recitations of the dependent claims are neither taught nor suggested by the cited references in the context of their combination with claim 1 or claim 11.

### CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (847) 432-7302 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date July 20, 2009

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 25th day of July, 2009.

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Name

Signature